JUL 7 - 2005

K051717

ATTACHMENT 6

510(k) Summary

1. **Applicant's Name and Address**

Straumann Manufacturing (on behalf of Institut Straumann AG)
60 Minuteman Road
Andover, MA 01810

Telephone Number:	978-747-2500
Fax Number:	978-747-0031
Contact Person:	Linda Jalbert Vice President, Regulatory & Clinical Affairs

2. **Name of the Device**

Trade Name:	RN synOcta Temporary Meso Abutment
Common Name:	Endosseous Dental Implant Abutment
Classification Name:	Endosseous Dental Implant Abutment

3. **Legally Marketed Devices to which Equivalence is Claimed (Predicate Devices)**

synOcta Post for Temporary Restoration, K990342
RN synOcta UCLA gold Abutment, K041295
ITI Protection Healing Caps, K962023

4. **Description of the Device**

RN synOcta Temporary Meso Abutment is a temporary abutment made of medical grade plastic, PEEK that allows for immediate temporization by the clinician. This plastic structure can be customized by the clinician and serves as a base for direct veneering or cemented restoration. The abutment is strengthened by an inlay of Titanium alloy that fits precisely into the Straumann Regular Neck (RN) implants. It is substantially equivalent in design and intended use with the previously cleared synOcta Post for temporary restoration, K990342.

5. **Intended Use of the Device**

Like the predicate device, synOcta Post for temporary restoration, the RN synOcta Temporary Meso Abutment is indicated for temporary restorations in the anterior and posterior region for up to 6 months.

6. **Basis for Substantial Equivalence**

The Straumann synOcta Temporary Meso Abutment is substantially equivalent to the previously cleared synOcta Post for temporary restoration, K990342. The intended use is identical to that of the predicate synOcta Post for temporary restoration. The design is also very similar to this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 7 - 2005

Institut Straumann SA
C/O Ms. Linda Jalbert
President of Regulatory & Clinical Affairs
Straumann USA
60 Minuteman Road
Andover, Massachusetts 01810

Re: K051717
Trade/Device Name: RN synOcta Temporary Meso Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: June 23, 2005
Received: June 27, 2005

Dear Ms. Jalbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051717

Device Name: RN synOcta Temporary Meso Abutment

Indications for Use:

RN SynOcta Temporary Meso Abutments are for use in RN Straumann Dental Implants (Ø4.8mm) for temporary restoration of single crowns in the anterior and posterior region for use up to six months.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kei Mulay for MSP

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K051717